

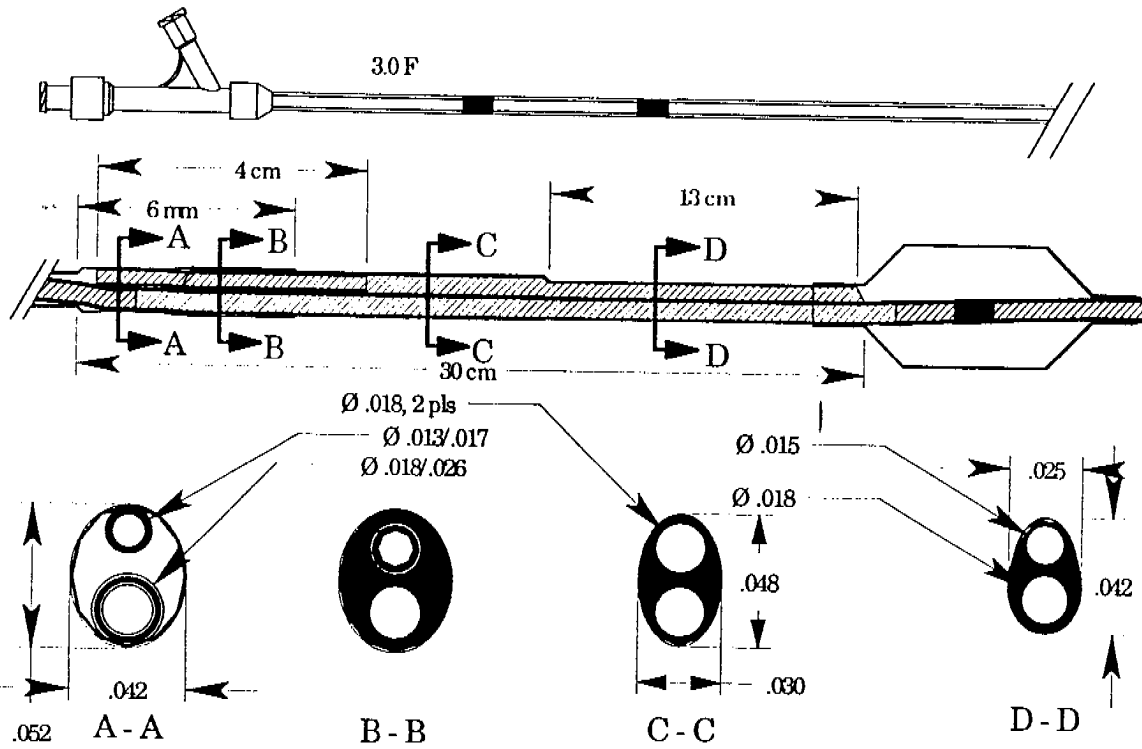
# Exhibit 35

*Eric Wilt 6/24/94*

CONFIDENTIAL

# .014 Platform Elliptical OTW

Dan Cox  
6-10-94



*MR Cherry 6/24/94*

*Eric Wilt 6/24/94*



Advanced Cardiovascular Systems, Inc.

# ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

*E. Will* 6/24/94

Product: <u>214 Platform OTW</u>	Date: <u>5/27/94</u>
Project Engineer: <u>Dan Cox</u>	Wet: <input checked="" type="checkbox"/> Dry: <input type="checkbox"/>
Clinical Research Coordinator: <u>Colleen McQueen</u>	
Control Catheter Used: _____	
Guiding Catheter: <u>TF TE 3.5 PG</u>	Guide Wire: <u>Tricus 3P</u>

① Product design/performance goals: <sup>3.0 F</sup>  
Coaxial distal PEEK Proximal, Graphite / PE Inner member  
Arden GUD distal outer shaft 3.9 F to 2.7 F, 3.0 PEGOO

1. Tip softness:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>not too stiff</u>					
2. Tip length:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>Acceptable, like level</u>					
3. Smoothness of transition:					
A. Distal tip to balloon:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
B. Balloon to shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
C. Shaft transitions:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>A: Transitionless very nice</u> <u>B: Pretty good</u> <u>C: A little stiff</u> <u>arcs pretty well</u>					
4. Flexibility of shaft:					
A. Proximal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
B. Distal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>A: Stiff</u> <u>B: Flexible</u> <u>both nice</u>					

(See Reverse)

*E. Will* 6/24/94

*VR Cherry*

6/24/94  
E. Webb

5. Ease of prep:	Prep method: _____	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____							
6. Inflation and deflation times:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>		
Inflation time: _____ Deflation time: _____							
Contrast & dilution: _____ Inflation device: _____							
Comments: _____							
7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>		
Comments: _____							
8. Trackability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>		
Comments: <u>Takes tight radius real well</u>							
9. Pushability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>		
Comments: <u>Good 1:1 transmission</u>							
10. Guide back out:	Yes _____	No _____	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>No guide movement lightly seated in OAG lesion</u>							
11. Guide wire movement:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>		
Comments: <u>Outside model 4.8/5.0</u>							
12. Dimensions (list size and area):	_____ _____ _____						
13. Old product meet design goals?	Yes _____	No _____					
Overall comments: _____ _____ _____							
Recommend For Animal Studies?							
Yes _____ No _____ N/A _____							

E. Webb 6/24/94

6/24/94  
M. Cheng



Advanced Cardiovascular Systems, Inc.

# ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Enc. Webb - 6/24/94

Product: 014 Platform OTW	Date: 5/27/94
Project Engineer: Don Cox	Wet: <input checked="" type="checkbox"/> Dry: <input type="checkbox"/>
Clinical Research Coordinator: Colleen McQueen	
Control Catheter Used:	
Guiding Catheter:	Guide Wire:

② Product design/performance goals:  
 Elliptical distal. Coaxial proximal 3.0 F PEEK, graphite/PE inner member  
 Distal necked from .029/.049 to .024/.045 about 3.0 PE GDO

1. Tip softness:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments:					
2. Tip length:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: Looks a little longer than ① Looks nice					
3. Smoothness of transition:					
A. Distal to balloon:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
B. Balloon to shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
C. Shaft transitions:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input checked="" type="radio"/>	Significantly Worse <input type="radio"/>
Comments: A: More step up to Gld B: Rough at transition had a bump C: About like ① A little more noticeable because distal is softer. Kinkable at hub. 4.2 step change is 4.3 by ①					
4. Flexibility of shaft:					
A. Proximal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input checked="" type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
B. Distal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input checked="" type="radio"/>	Significantly Worse <input type="radio"/>
Comments: A: Wimpier on distal necked section Unnecked Balright but wimpier than ①					

UR Cherry 6/24/94

(See Reverse)

Enc. Webb 6/24/94

5. Ease of prep: Prep method: \_\_\_\_\_  
 Significantly Better ☐ Somewhat Better ☐ Same As ☐ Somewhat Worse ☐ Significantly Worse ☐  
 Comments: \_\_\_\_\_

6. Inflation and deflation times: \_\_\_\_\_  
 Significantly Better ☐ Somewhat Better ☐ Same As ☐ Somewhat Worse ☐ Significantly Worse ☐  
 Inflation time: \_\_\_\_\_ Deflation time: \_\_\_\_\_  
 Contrast & dilution: \_\_\_\_\_ Inflation device: \_\_\_\_\_  
 Comments: \_\_\_\_\_

7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding): \_\_\_\_\_  
 Significantly Better ☐ Somewhat Better ☐ Same As ☐ Somewhat Worse ☐ Significantly Worse ☐  
 Comments: \_\_\_\_\_

8. Trackability: \_\_\_\_\_  
 Significantly Better ☐ Somewhat Better ☐ Same As ☒ Somewhat Worse ☐ Significantly Worse ☐  
 Comments: Can feel proximal transition but still tracks well

9. Pushability: \_\_\_\_\_  
 Significantly Better ☐ Somewhat Better ☐ Same As ☒ Somewhat Worse ☐ Significantly Worse ☐  
 Comments: \_\_\_\_\_

10. Guide back out: Yes \_\_\_\_\_ No \_\_\_\_\_  
 Significantly Better ☐ Somewhat Better ☐ Same As ☐ Somewhat Worse ☐ Significantly Worse ☐  
 Comments: No backout until proximal seal hit lesion

11. Guide wire movement: \_\_\_\_\_  
 Significantly Better ☐ Somewhat Better ☐ Same As ☐ Somewhat Worse ☒ Significantly Worse ☐  
 Comments: Sticky

12. Dimensions (Ist size and area): \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

13. Did product meet design goals? Yes \_\_\_\_\_ No \_\_\_\_\_  
 Overall comments: Slight performance Edge for coaxial in wire movement  
 \_\_\_\_\_  
 \_\_\_\_\_

Recommend For Animal Studies?  
 Yes \_\_\_\_\_ No \_\_\_\_\_ N/A \_\_\_\_\_

*E. Webb 6/24/94*

*W. Chawry 6/24/94*

*EC With 6/24/94*

Date: 6/21/94

Title: Coax w/PEEK - Elliptical Distal (with a 100% HDPE a 75/25 HDPE/LLDPE and a 83/13/4 HDPE/LLDPE/GRAPHITE distal elliptical)

Objective: To evaluate these catheters to determine if the stiffer materials (100%HDPE and 83%/13% 4% HDPE/LLDPE/GRAPHITE) perform better than the softer 75/25 material. I.e., prevent prolapse

Procedure: Note: Ref drawing for dimensions

Tooling: .011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.  
.025, .031, .039, .043 and .048 Teflon capture tubing.  
Razor blades, Hot box, and Induction heater

**Materials:**

Description	Part Number	Comments
Elliptical dual lumen	N/A R&D	75/25 Alathon/LDPE
Elliptical dual lumen	Ext. # 10-465-T	100% HDPE
Elliptical dual lumen	Ext. # 12-194-B	83% HDPE w/13% LLDPE + 4% Graphite
IM	Ext. # 13-88-A	Graphite
Intermediate shaft	Ext. # 12-083	Alathon 6210
IM	Ext. # V-466-1	Graphite
Stiff Shaft	Vendor# 02-149	PEEK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	-----
Distal tip Material	Ext. # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	-----
Gold Bands	RM500340	-----
Loctite	RM60563	414
Loctite	RM60124	420
Loctite	RM60562	350

**Assembly Instructions: (Distal Elliptical)**

- Cut approximately 40 cm of the elliptical shaped tubing.
- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to .026 x .045 +/- .001.
- Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

**Distal Tip:**

- Cut the graphite to approximately 20 cm.
- Neck the graphite to .021 OD using an autonecker.
- Parameters: Temp = 290°f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm
- Slide the gold band over the necked portion.

*IR Cherry 6/24/94*

*EC With 6/24/94*

E. Wall 6/24/94

- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f
- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

#### Balloon Seal:

- Expand proximal balloon shaft in a .048 ID capture tube.
- Trim to 7mm
- Insert a .015 mandrel into the inflation lumen.
- Slide .039 oval split sheath onto catheter.
- Slide sheath over proximal portion of the balloon and heat seal at 350° f
- Flatten with a flat smooth block
- Remove inflation/deflation mandrel.
- Tip seal using a "Balloon Buncher Tip Sealer"
- Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"

#### Proximal End:

- Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.
- Insert two-.018 Teflon coated mandrels into both lumens.
- Neck using an autonecker.
- Parameters: Temp = 270° f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

#### Inner Member Assembly:

- Cut a 125cm piece of Graphite inner member material.
- Insert a .017 mandrel through the Graphite.
- Neck the Graphite to .021 OD using an autonecker.
- Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.
- Insert the necked graphite into the flared guidewire lumen.
- Insert a .012 mandrel into the Polyimide.
- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel tubing.
- Parameters: Temp = 350° f (Hot Box)
- Remove the .012 mandrel from the Polyimide.

#### Proximal Shaft Assembly:

- Cut a 110cm piece of PEEK.
- Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)
- Trim the expanded portion 5-6mm
- Cut the PEEK 102 cm from the proximal end of the expanded portion.
- Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420
- Note: do not allow the adhesive to wick into the Polyimide tubing.
- Note: do not force the unexpanded PEEK over the Inflation lumen.

6/24/94 [Signature]

E. Wall 6/24/94



*in with 6/24/94*

**Two-Arm Assembly:**

- Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. *Note: use a .018 Teflon mandrel in the graphite.*
- Attach the IM cup to the twoarm with a centerport.
- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350
- Attach the OM cup to the twoarm and tighten the nosecone and centerport
- UV cure on each side of the nosecone for 50 seconds.

**Final Assembly:**

- Trim tip to 3.0mm
- Tip Sand
- Microglide and Sheath

**Conclusion:** The 100% HDPE and the 83/13/4 blend performed better than the 75/25 LLDPE catheters. The 83/13/4 blend tracked over the wire with ease. It was mentioned that "this is the best I have seen in a while" the guidewire movement was rated 3.75 on a scale of 1 -5 with 5 being the best. Both the 100% and the 83/13/4% blend had good push however the 100% was slightly better. The 100% HDPE and the 83/13/4% blend seem to follow the wire and was less prone to prolapsing whereas the 75/25% seem to press up against the walls of the artery. (for more details see heart model evaluation notes)

*RC Henry 6/24/94*

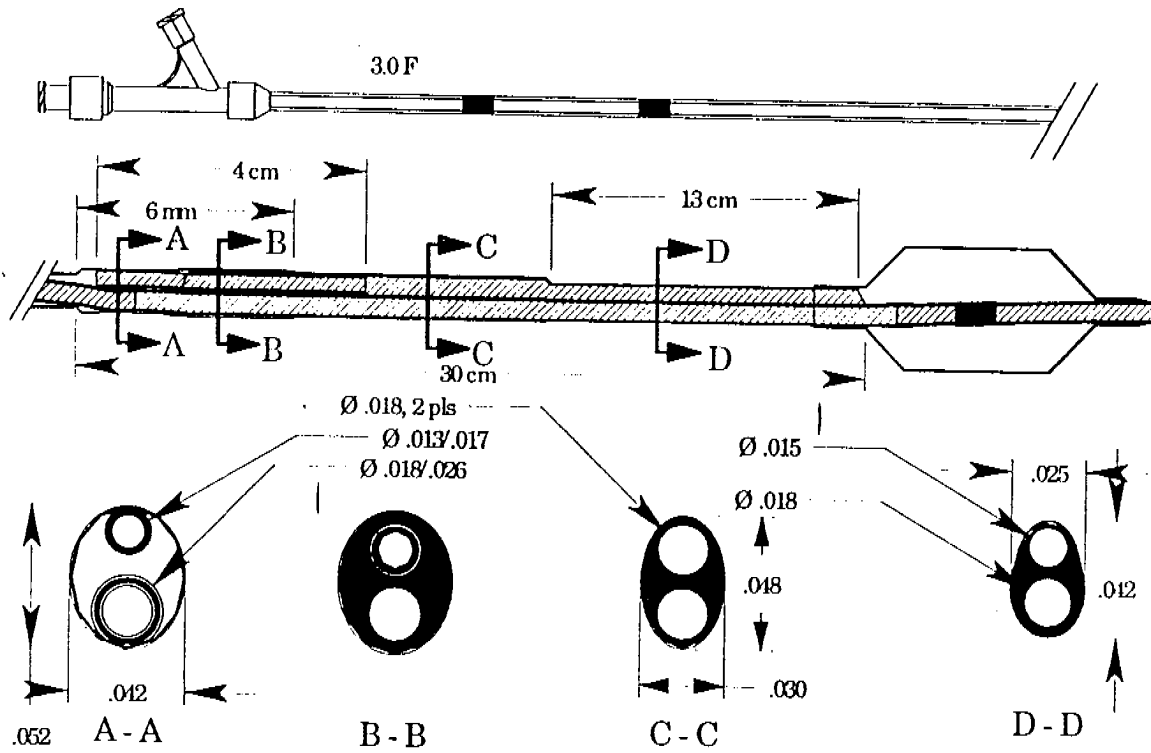
*in with 6/24/94*

*En Will 6/24/94*

CONFIDENTIAL

# .014 Platform Elliptical OTW

Dan Cox  
6-10-94



*VR Chernys  
6/24/94*

*En Will 6/24/94*



Advanced Cardiovascular Systems, Inc.

## ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 6/20/94  
 Project Engineer: Dan Cox Wet: ☒ Dry: ☐  
 Clinical Research Coordinator: Colleen McQueen  
 Control Catheter Used: NonP  
 Guiding Catheter: TF JL3.5 PG Guide Wire: HTF TT

①

Product design/performance goals:

PEEK Proximal outer shaft, Graphite/PE inner member; Coaxial  
Proximal, elliptical dual lumen distally. Dual lumen is HDPE (clear)

1. Tip softness:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: _____					
2. Tip length:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: _____					
3. Smoothness of transition:					
A. Distal to to balloon:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
B. Balloon to snart	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
C. Snart transitions:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: <u>B: Pretty smooth looks good</u> <u>C: A little rough</u>					
4. Flexibility of shaft:					
A. Proximal snart:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
B. Distal snart:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: <u>B: Good</u>					

M Cherry 6/24/94

(See Reverse)

E. W. 6/24/94

Ex With 6/24/94

5. Ease of prep:	Prep method: _____	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: _____						
6. Inflation and deflation times:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Inflation time: _____		Deflation time: _____				
Contrast & dilation: _____		Inflation device: _____				
Comments: _____						
7. General appearance of dilation catheter during inflation and deflation (note bowing and folding):	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____						
8. Trackability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Tracks well. Front and flexible enough to track very well</u>						
9. Pushability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Has good push. Transmits push 1:1. Follows shape of guidewire</u>						
10. Guide back out:	Significantly Better <input type="radio"/>	Yes _____ Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	No _____ Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____						
11. Guide wire movement:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>A little heavy 3.75 in septal</u>						
12. Dimensions (list size and area):	_____ _____ _____					
13. Did product meet design goals?	Yes _____		No _____			
Overall comments: <u>Lesion in septal is .0445". With 0.37" lesion in diagonal it does not squeeze off when pushing as much as (3). About like (2).</u>						
Recommend For Animal Studies?						
Yes _____		No _____		NA _____		

6/24/94  
R Cherry

Ex With 6/24/94



Advanced Cardiovascular Systems, Inc.

## ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

E. W. 6/24/94

Product: <u>114 Platform OTW</u>	Date: <u>6/20/94</u>
Project Engineer: _____	Wet: _____ Dry: _____
Clinical Research Coordinator: _____	
Control Catheter Used: _____	
Guiding Catheter: _____	Guide Wire: _____

② Product design/performance goals: Same as ① except dual lumen is 83% HDPE/13% LLDPE/4% graphite

1. Tip softness:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: _____					
2. Tip length:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: _____					
3. Smoothness of transition:					
A. Distal up to balloon:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
B. Balloon to snart:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
C. Snart transitions:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: <u>B: Same as ①</u> <u>C: Seems a little shorter and less ledge than ①, but still a little ledge.</u>					
4. Flexibility of snart:					
A. Proximal snart:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
B. Distal snart:	Significantly Better <input type="checkbox"/>	Somewhat Better <input type="checkbox"/>	Same As <input type="checkbox"/>	Somewhat Worse <input type="checkbox"/>	Significantly Worse <input type="checkbox"/>
Comments: <u>B: About same as ①. Maybe a little more flexible than ①</u>					

(See Reverse)

W. Channing  
6/24/94

E. W. 6/24/94

See within 6/24/94

5. Ease of prep:	Prep method:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: _____						
6. Inflation and deflation times:	Inflation time: _____	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Deflation time: _____						
Contrast & dilution: _____						
Inflation device: _____						
Comments: _____						
7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____						
8. Trackability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Tracked better than ① until it hit lesion</u>						
9. Pushability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Follows wire same as ① Pushes better than ① Good back and push</u>						
10. Guide back out:	Yes _____	No _____				
Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>		
Comments: <u>Like a steak effortless to cross lesion and profile seems better bigger than ①</u>						
11. Guide wire movement:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>3.5 in septal No big differences to ①</u>						
12. Dimensions (list size and area):	_____ _____ _____					
13. Did product meet design goals?	Yes _____	No _____				
Overall comments: <u>With 037 lesion in diagonal this still tracked the best and did not square all in the artery like ③. This is the best catheter overall.</u>						
Recommend For Animal Studies?						
Yes _____		No _____		N/A _____		

See within 6/24/94

W. Cherry  
6/24/94



Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: Q14 Platform OTW Date: 6/20/94  
Project Engineer: \_\_\_\_\_ Wet: \_\_\_\_\_ Dry: \_\_\_\_\_  
Clinical Research Coordinator: \_\_\_\_\_  
Control Catheter Used: \_\_\_\_\_  
Guiding Catheter: \_\_\_\_\_ Guide Wire: \_\_\_\_\_

Product design/performance goals:

Same as ① except dual lumen is 75% HDPE / 25% LLDPE (white)

1. Tip softness:

Significantly  
Better  
☐

Somewhat  
Better  
☐

Same As  
☐

Somewhat  
Worse  
☐

Significantly  
Worse  
☐

Comments: \_\_\_\_\_

2. Tip length:

Significantly  
Better  
☐

Somewhat  
Better  
☐

Same As  
☐

Somewhat  
Worse  
☐

Significantly  
Worse  
☐

Comments: \_\_\_\_\_

3. Smoothness of transition:

A. Distal tip to balloon:

Significantly  
Better  
☐

Somewhat  
Better  
☐

Same As  
☐

Somewhat  
Worse  
☐

Significantly  
Worse  
☐

B. Balloon to shaft:

Significantly  
Better  
☐

Somewhat  
Better  
☐

Same As  
☐

Somewhat  
Worse  
☐

Significantly  
Worse  
☐

C. Shaft transitions:

Significantly  
Better  
☐

Somewhat  
Better  
☐

Same As  
☐

Somewhat  
Worse  
☐

Significantly  
Worse  
☐

Comments: B: Good size and smooth  
C: Nice and smooth best of all

4. Flexibility of shaft:

A. Proximal shaft:

Significantly  
Better  
☐

Somewhat  
Better  
☐

Same As  
☐

Somewhat  
Worse  
☐

Significantly  
Worse  
☐

B. Distal shaft:

Significantly  
Better  
☐

Somewhat  
Better  
☐

Same As  
☐

Somewhat  
Worse  
☐

Significantly  
Worse  
☐

Comments: B: Less stiff than ① about same as ②

W. Cherry 6/24/94

(See Reverse)

En White 6/24/94

5. Ease of prep:	Prep method: _____	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: _____						
6. Inflation and deflation times:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Inflation time: _____		Deflation time: _____				
Contrast & dilution: _____		Inflation device: _____				
Comments: _____						
7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____						
8. Trackability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: About same as (1) Not as good as (2)						
9. Pushability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: Push is pretty good. Doesn't square off in vessel like 1 when you push.						
10. Guide back out:	Yes _____	No _____	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>
Comments: _____						
11. Guide wire movement:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: Pretty good. 3.75 in septal.						
12. Dimensions (list size and area): _____ _____ _____						
13. Did product meet design goals? Yes _____ No _____						
Overall comments: Tracked well to 037 lesion in diagonal, but catheter squared off in artery when pushing against lesion						
Recommend For Animal Studies? Yes _____ No _____ N/A _____						



PROPERTY OF ADVANCED CARDIOVASCULAR SYSTEMS, INC.



Advanced Cardiovascular Systems, Inc.

3200 Lakeside Drive

P.O. Box 58167

Santa Clara, CA 95052-8167

NAME ERIC WILLIAMS  
DEPT. 1471  
LAB. NOTEBOOK NO. 1220  
ISSUE DATE 08/20/93  
RETURN DATE 8/11/94

RETURN TO DOCUMENT CONTROL FOR ARCHIVING.

15555 45048

date: 5/25/94

Title: Shaft Material Evaluation

Objective: To evaluate various potential shaft materials

Materials: EVAL Extrusion # 12-143A, EVAL Extrusion # 12-142A, AERN Nylon Ext # 11-221-1, Grivory Nylon Ext # 10-547-6, Grivory Nylon Ext # 10-548-1, PPS Ext # 10-556-1, Isoplast Ext # 10-531-1, PEEK 381G and PES Ext # 10-576-1

Procedure: Rupture test 10 samples of the EVAL material and 5 samples each of the other materials. Parameters: Water Temp=37degC, Start Pressure=60psi, Increments=15psi, Hold time=15sec

Results:

Material	Ext #	ID/OD	Average Rupt	Std Dev					
EVAL	12-143A	.017/.021	217.51	14.57738					
EVAL	12-142A	.032/.038	1231	6.3245553					
AERN NYLON	11-221-1	.031/.038	291	8.2158384					
GRIVORY NYLON	10-547-6	.032/.039	414	8.2158384					
GRIVORY NYLON	10-548-1	.018/.025	500	8.2158384					
ISOPLAT	10-531-1	.031/.038	387	16.431677					
PPS	10-556-1	.031/.038	411	8.2158384					
PES	10-576-1	.032/.039	500	0					
PEEK	N/A	.032/.038	500	0					

Material	Sample #	Rupture	Material	Sample #	Rupture	Material	Sample #	Rupture
EVAL (Inner Mem)	1	210	EVAL	1	120	AERN	1	300
	2	255		2	120		2	285
	3	210		3	120		3	300
	4	210		4	120		4	285
	5	210		5	135		5	285
	6	210		6	120		6	
	7	210		7	120		7	
	8	210		8	135		8	
	9	225		9	120		9	
	10	225		10	120		10	

Material	Sample #	Rupture	Material	Sample #	Rupture	Material	Sample #	Rupture
GRIVORY 547	1	405	GRIVORY 548	1	500	PEEK	1	500
	2	420		2	500		2	500
	3	405		3	500		3	500
	4	420		4	500		4	500
	5	420		5	500		5	500

Material	Sample #	Rupture	Material	Sample #	Rupture	Material	Sample #	Rupture
ISOPLAT	1	375	PPS	1	405	PES	1	500
	2	375		2	405		2	500
	3	405		3	420		3	500
	4	405		4	420		4	500
	5	375		5	405		5	500

5/15/94 J. W. Wang

Jim W. Wang 5/25/94

ate; 5/27/94

Date: 5/27/94

Title: PEEK To Elliptical Transition Development

Objective: To evaluate various concepts for improving the transition from the PEEK outer shaft to the elliptical distal dual lumen.

Materials: Graphite Extrusion V-466-1, PEEK 3816, HDPE SA200247, Alethon Extrusion 12-083, Stainless Steel .007&gt;.003 mandrels, Polyimide "Hudson" .013 x .017, and Loctite 414

Procedure:

Concept 1

*PEEK to Elliptical.* Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Concept 2

*PEEK to Elliptical with Intermediate Shaft.* Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f Cut a 3cm piece of HDPE flare one end so that it fits over the elliptical tubing. Using a .045 Teflon capture tube heat bond the HDPE to the elliptical tubing. Flare one end of the PEEK to an ID that will allow it to fit over the HDPE. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

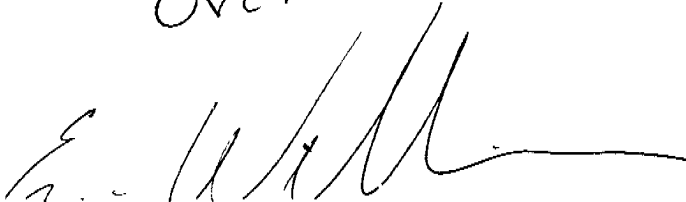
Concept 3

*PEEK to Elliptical with .007>.003 tapered mandrel in the inflation lumen.* Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F trim to 5mm remove mandrel from one of the lumens and insert a 4 cm of tapered mandrel inside that lumen wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Conclusion: Concept 1 was easily assembled and had a fairly good transition from PEEK to elliptical due primarily to the Polyimide in the inflation lumen; the joint was smooth and had an OD of .040x.046. Concept 2 required additional steps to build and yet it was inconclusive about which had a better transition. The OD measured .040x.047. Concept 3 had an improved transition over the first two however it was far more difficult to assemble and the wire was too large and could possibly impede deflation.

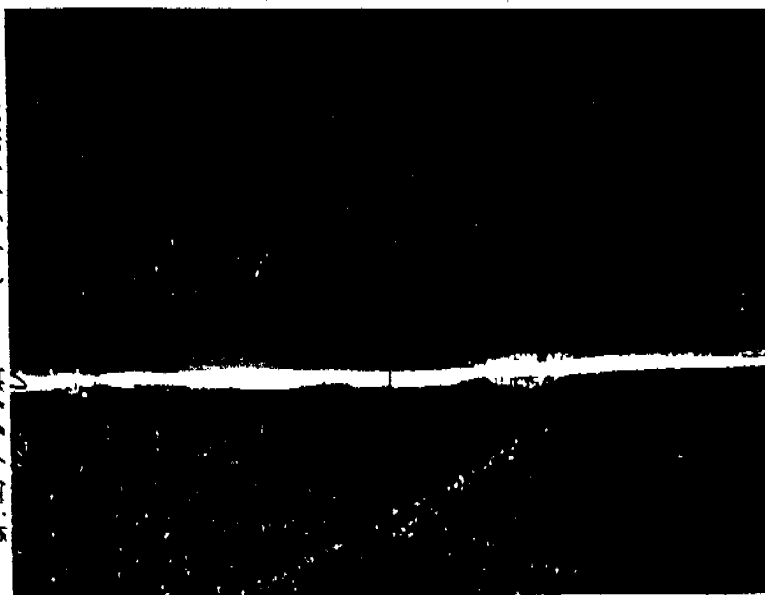
for William 5/27/94

OVER →


 5/27/94

 V. Williams  
 6/15/94

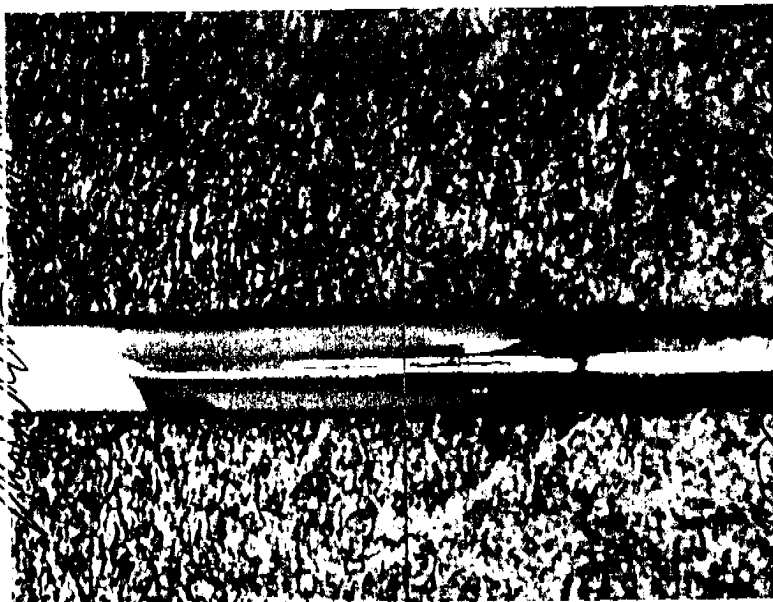
5-11-11 5/15/94



5/15/94  
M. Kelly

Concept 1

5-11-11 5/15/94



5/15/94  
M. Kelly

Concept 2

5-11-11 5/15/94



5/15/94  
M. Kelly

ate: 5/27/94

Date: 5/27/94

Title: PEEK to Elliptical Intermediate vs No Intermediate Shaft

Objective: To compare and evaluate the performance of a PEEK to elliptical OTW catheter with and without an intermediate shaft.

Procedure:

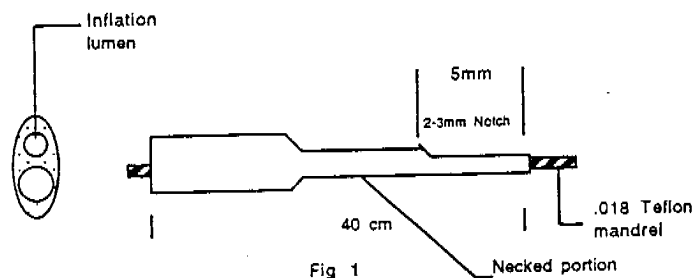
Tooling: .011, .017, .018, .024, .026, .028, .031 and .040 Teflon coated mandrels.  
.025, .031, .039, .043 and .048 Teflon capture tubing.  
Razor blades, Hot box, and Induction heater

Materials:

Description	Part Number	Comments
Elliptical dual lumen	<del>Ext # 12-110A</del>	75/25 Alathon/LDPE
Intermediate shaft	Ext # 12-083	Alathon 6210
IM	Ext # V-466-1	Graphite
Stuff Shaft	Vendor# 02-149	PEEK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	
Distal tip Material	Ext # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	
Gold Bands	RM500340	
Loctite	RM60563	414
Loctite	RM60124	420
Loctite	RM60562	350

Assembly Instructions: (Distal Elliptical)

- Cut approximately 40 cm of the elliptical shaped tubing.
- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to .026 x .045 +/- .001.
- Parameters: Temp = 270°F Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)



*EW* 5/27/94

*EW* 5/27/94

*EW*  
6/5/94

38

**Distal Tip:**

- Cut the graphite to approximately 20 cm.
- Neck the graphite to .021 OD using an autonecker.
- Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm
- Slide the gold band over the necked portion.
- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f
- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

**Balloon Seal:**

- Expand proximal balloon shaft in a .048 ID capture tube.
- Trim to 7mm
- Insert a .015 mandrel into the inflation lumen.
- Slide .039 oval split sheath onto catheter.
- Slide sheath over proximal portion of the balloon and heat seal at 350° f
- Remove inflation/deflation mandrel.
- Tip seal using a "Balloon Buncher Tip Sealer"
- Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"

**Proximal End:**

- Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.
- Insert two-.018 Teflon coated mandrels into both lumens.
- Neck using an autonecker.
- Parameters: Temp = 270° f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of polyimide into the inflation lumen. Tack the polyimide into place with a drop of Loctite 420.

**Inner Member Assembly:**

- Cut a 160cm piece of Graphite inner member material.
- Insert a .017 mandrel through the Graphite.
- Neck the Graphite to .021 OD using an autonecker.
- Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.
- Insert the necked graphite into the flared guidewire lumen.
- Insert a .012 mandrel into the polyimide.
- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel tubing.
- Parameters: Temp = 350° f (Hot Box)
- Remove the .012 mandrel from the polyimide.

**Proximal Shaft Assembly:**

- Cut a 110cm piece of PEEK.
  - Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)
  - Trim the expanded portion 5-6mm
  - Cut the PEEK 102 cm from the proximal end of the expanded portion.
  - Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420
- Note: do not allow the adhesive to wick into the polyimide tubing.*  
*Note: do not force the unexpanded PEEK over the Inflation lumen.*

*W. Chong 6/15/94*

*Em Withers 5/27/94*

*Em Withers 5/27/94*

**Two-Arm Assembly:**

- Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350°  
f. *Note: use a .018 Teflon mandrel in the graphite.*
- Attach the IM cup to the twoarm with a centerport.
- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350
- Attach the OM cup to the twoarm and tighten the nosecone and centerport
- UV cure on each side of the nosecone for 50 seconds.

**Final Assembly:**

- Trim tip to 3.0mm
- Tip Sand
- Microglide and Sheath

Ref: Drawing ON pg For  
dimensions, E.W 6-15-94

**Conclusion:** Note: the Catheters built with an intermediate shaft were built by Kim Nguyen ref Lab notebook # 1152. The Catheters were compared in a heart model and it was determined that there was little difference in the two catheters performance, however neither catheter performed very well in comparison to our coaxial design. The proximal balloon seals were perceived as stiff and having an abrupt transition.

**Recommendation:** Rebuild using the "no intermediate shaft" and improve the proximal balloon seal stiffness and transition. Evaluate in a heart model.

Ref: heart model Results  
Next page E.W 6-15-94

Em With 5/27/94

6/15/94  
H. Nguyen

Em With 5/27/94

6/21/94



Advanced Cardiovascular Systems, Inc.

# ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: <u>014 Platform OTW</u>	Date: <u>5/20/94</u>
Project Engineer: <u>Dan Cox</u>	Wet: <input checked="" type="checkbox"/> Dry: <input type="checkbox"/>
Clinical Research Coordinator: <u>Ron Seyna</u>	
Control Catheter Used: _____	
Guiding Catheter: <u>7F JLA PG</u>	Guide Wire: _____

① Product design/performance goals:  
Coaxial OTW, PEEK proximal outer shaft graphite PE inner member  
Alumina 6210 distal shaft 2.7F PEGOO 3.0 mm Balloon

1. Tip softness:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>Nice taper, smooth</u>					
2. Tip length:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: _____					
3. Smoothness of transition:					
A. Distal to to balloon:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Nice folding					
B. Balloon to shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Can feel transition					
C. Shaft transitions:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Can feel PEEK/PE junction					
Comments: <u>Transitions noticeable but not a problem</u>					
4. Flexibility of shaft:					
A. Proximal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
B. Distal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>Very nice</u>					

*[Signature]*  
6/24/94

R&Q/2/HATTES5.QMS

(See Reverse)

*[Signature]* 6/21/94

11/16/92

*[Signature]* 6/21/94



6/21/94

2

5. Ease of prep:	Prep method:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>Fine</u>						
6. Inflation and deflation times:	Inflation time:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Deflation time: <u>9 sec</u>		Contrast & diffusion: _____ Inflation device: _____				
Comments: <u>No bowing</u>						
7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____						
8. Trackability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Tip came around bend nicely. Took contour of wire nicely</u>						
9. Pushability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Very nice. After 8 atm 60 sec no support got 70% into lesion and with support got all the way into lesion</u>						
10. Guide back out:	Yes _____	No _____	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>Fully sheathed itself (1043) with light guide support</u>						
11. Guide wire movement:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Initially smooth, slightly heavier in septal</u>						
12. Dimensions (list size and area): _____ _____ _____						
13. Did product meet design goals? Yes _____ No _____						
Overall comments: <u>Followed contour of wire even with hard pushing. Got it to kink and prolapse like ② except a lot more difficult to prolapse</u>						
Recommend For Animal Studies? Yes _____ No _____ N/A _____						

R&amp;D/2/HRTTESTS.QMS

11/15/92

2  
 E. With 6/21/94

E. With 6/21/94

6/24/94  
 M. Long

6/21/94



Advanced Cardiovascular Systems, Inc.

## ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

3

Product: 014 Platform OTW	Date: 5/20/94
Project Engineer: GSK	Wet: _____ Dry: _____
Clinical Research Coordinator: Sejna	
Control Catheter Used: _____	
Guiding Catheter: _____	Guide Wire: _____

## Product design/performance goals:

② Coaxial proximal PEEK outer shaft, graphite PE inner member  
75% HDPE/25% LLOPE elliptical distal shaft 3.0 mm PEG00

1. Tip softness:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input checked="" type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: _____					
2. Tip length:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input checked="" type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: _____					
3. Smoothness of transition:					
A. Distal tip to balloon:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input checked="" type="radio"/>	Significantly Worse <input type="radio"/>
Not as nice as ① in fold					
B. Balloon to shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input checked="" type="radio"/>	Significantly Worse <input type="radio"/>
Smother than ① but bulky compared to shaft					
C. Shaft transitions:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Nice, smooth					
Comments: B in abruptness, not a lot					
4. Flexibility of shaft:					
A. Proximal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
B. Distal shaft:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: B: A little more flexible, not necessarily better					

R&amp;D/2/HRTTEST5.CMS

(See Reverse)

11/16/92

W. Cherry  
6/24/94

E. With 6/21/94

E. With 6/21/94

21/94

4

5. Ease of prep:	Prep method:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: <u>Fine</u>						
6. Inflation and deflation times:	Inflation time:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Deflation time: <u>8 sec</u>						
Contrast & dilution: _____ Inflation device: _____						
Comments: <u>Bowing at 8 atm like (3)</u>						
7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____						
8. Trackability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input checked="" type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Proximal seal was stiff, did not 90° around bend into septal</u> <u>Does not hug wire like (1)</u>						
9. Pushability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input checked="" type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Good fully sheathed w guide support, After 8 atm, got front of</u> <u>balloon into 045 lesion. Got all the way in with guide support.</u>						
10. Guide back out:	Yes _____	No _____				
Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>		
Comments: <u>Lightly seated just got tip into lesion (043)</u>						
11. Guide wire movement:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Slightly worse than (1)</u>						
12. Dimensions (list size and area): _____ _____ _____						
13. Did product meet design goals? Yes _____ No _____						
Overall comments: <u>Kept pushing until distal shaft prolapse. It went into circ and LAD</u> <u>and kinked when balloon was stuck in lesion in septal</u>						
Recommend For Animal Studies? Yes _____ No _____ N/A _____						

Albany  
6/24/94

R&D/HATTEST3.CMS

gu = Uthman 6/21/94

11/16/92

E. Uthman 6/21/94



Advanced Cardiovascular Systems, Inc.

## ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 5/20/94  
 Project Engineer: Cox Wet: \_\_\_\_\_ Dry: \_\_\_\_\_  
 Clinical Research Coordinator: Sejoo  
 Control Catheter Used: \_\_\_\_\_  
 Guiding Catheter: \_\_\_\_\_ Guide Wire: \_\_\_\_\_

## Product design/performance goals:

③

Same as ② except has 10 cm intermediate Alator shaft between  
 elliptical distal and PEEK 3.0 mm PEG00

## 1. Tip softness:

Significantly  
Better  
☐Somewhat  
Better  
☐Same As  
☐Somewhat  
Worse  
☐Significantly  
Worse  
☐Comments: Nice taper

## 2. Tip length:

Significantly  
Better  
☐Somewhat  
Better  
☐Same As  
☐Somewhat  
Worse  
☐Significantly  
Worse  
☐Comments: A little shorter

## 3. Smoothness of transition:

## A. Distal tip to balloon:

Significantly  
Better  
☐Somewhat  
Better  
☐Same As  
☒Somewhat  
Worse  
☐Significantly  
Worse  
☐

## B. Balloon to shaft:

Significantly  
Better  
☐Somewhat  
Better  
☐Same As  
☐Somewhat  
Worse  
☒Significantly  
Worse  
☐

Like ②

## C. Shaft transitions:

Significantly  
Better  
☐Somewhat  
Better  
☐Same As  
☐Somewhat  
Worse  
☐Significantly  
Worse  
☐

Comments: C: Both transitions are nice and smooth. More subtle switch from PEEK  
 to elliptical. PEEK to PE feels like ①, PE to elliptical is nice.

## 4. Flexibility of shaft:

## A. Proximal shaft:

Significantly  
Better  
☐Somewhat  
Better  
☐Same As  
☐Somewhat  
Worse  
☐Significantly  
Worse  
☐

## B. Distal shaft:

Significantly  
Better  
☐Somewhat  
Better  
☐Same As  
☐Somewhat  
Worse  
☐Significantly  
Worse  
☐

Same as ②

Comments: \_\_\_\_\_

R&amp;D/2/HRTTESTS.CMS

(See Reverse)

11/16/92

for Walter 6/21/94

for Walter 6/21/94

Walter  
6/24/94

5. Ease of prep:	Prep method:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>
Comments: _____						
6. Inflation and deflation times:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Inflation time: _____		Deflation time: <u>12 sec hard to see</u>				
Contrast & dilation: _____		Inflation device: _____				
Comments: <u>Same</u>						
7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Some bowing Inner member rides side of balloon at 8 atm.</u>						
8. Trackability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: _____						
9. Pushability:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Got 55% into lesion after 8 atm inflation. Good push Distal shaft would have prolapsed into circ with more pushing</u>						
10. Guide back out:	Yes _____			No _____		
	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Lightly seated got just shoulders into sheath</u>						
11. Guide wire movement:	Significantly Better <input type="radio"/>	Somewhat Better <input type="radio"/>	Same As <input type="radio"/>	Somewhat Worse <input checked="" type="radio"/>	Significantly Worse <input type="radio"/>	
Comments: <u>Not as good as ① or ② even before catheter in anatomy and after use.</u>						
12. Dimensions (list size and area):	<div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="border-bottom: 1px solid black; width: 100%;"></div>					
13. Old product meet design goals?	Yes _____			No _____		
Overall comments: <u>No noticeable effect due to change in transition from ②. Did not follow contour of wire with heavy pushing. Looked easier to prolapse than ①</u>						
Recommend For Animal Studies?						
Yes _____		No _____			N/A _____	

R&Q/2/MRTTESTS.QMS

*Eric With 6/24/94*

11/15/92

*W. Cherry 6/24/94*

*Eric With 6/21/94*

*Eric With* 6/24/94

Date: 6/21/94

Title: Coax w/PEEK - Elliptical

Objective: To evaluate these catheters ( with improved proximal balloon seal and guidewire movement) versus the catheters in the previous heart model. Ref pg. 57

Procedure: Note: Ref drawing for dimensions

Tooling: .011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.  
.025, .031, .039, .043 and .048 Teflon capture tubing.  
Razor blades, Hot box, and Induction heater

**Materials:**

Description	Part Number	Comments
Elliptical dual lumen	N/A R&D	75/25 Alathon/LDPE
Intermediate shaft	Ext. # 12-083	Alathon 6210
IM	Ext. # V-466-1	Graphite
Stiff Shaft	Vendor# 02-149	PEEK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	-----
Distal tip Material	Ext. # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	-----
Gold Bands	RM500340	-----
Loctite	RM60563	414
Loctite	RM60124	420
Loctite	RM60562	350

**Assembly Instructions: (Distal Elliptical)**

- Cut approximately 40 cm of the elliptical shaped tubing.
- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to .026 x .045 +/- .001.
- Parameters: Temp = 270° f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

**Distal Tip:**

- Cut the graphite to approximately 20 cm.
- Neck the graphite to .021 OD using an autonecker.
- Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm
- Slide the gold band over the necked portion.
- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f
- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

*W. Owens*  
6/24/94

*Eric With* 6/24/94

*E. Will 6/24/94*

**Balloon Seal:**

- Expand proximal balloon shaft in a .048 ID capture tube.
- Trim to 7mm
- Insert a .015 mandrel into the inflation lumen.
- Slide .039 oval split sheath onto catheter.
- Slide sheath over proximal portion of the balloon and heat seal at 350° f
- Flatten with a flat smooth block
- Remove inflation/deflation mandrel.
- Tip seal using a "Balloon Buncher Tip Sealer"
- **Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"**

**Proximal End:**

- Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.
- Insert two-.018 Teflon coated mandrels into both lumens.
- Neck using an autonecker.
- **Parameters: Temp = 270° f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm (trim to 1cm)**
- Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

**Inner Member Assembly:**

- Cut a 125cm piece of Graphite inner member material.
- Insert a .017 mandrel through the Graphite.
- Neck the Graphite to .021 OD using an autonecker.
- **Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm (trim to 4mm)**
- Flare the guidewire lumen with a .025 mandrel 1mm.
- Insert the necked graphite into the flared guidewire lumen.
- Insert a .012 mandrel into the Polyimide.
- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel tubing.
- **Parameters: Temp = 350° f (Hot Box)**
- Remove the .012 mandrel from the Polyimide.

**Proximal Shaft Assembly:**

- Cut a 110cm piece of PEEK.
- Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)
- Trim the expanded portion 5-6mm
- Cut the PEEK 102 cm from the proximal end of the expanded portion.
- Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420
- Note: do not allow the adhesive to wick into the Polyimide tubing.*
- Note: do not force the unexpanded PEEK over the Inflation lumen.*

*E. Will 6/24/94*

*McCherry  
6/24/94*

En Ullh 6/24/94

**Two-Arm Assembly:**

- Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. *Note: use a .018 Teflon mandrel in the graphite.*
- Attach the IM cup to the twoarm with a centerport.
- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350
- Attach the OM cup to the twoarm and tighten the nosecone and centerport
- UV cure on each side of the nosecone for 50 seconds.

**Final Assembly:**

- Trim tip to 3.0mm
- Tip Sand
- Microglide and Sheath

**Conclusion:** These catheters performed better then the catheters in the previous heart model. The proximal seals were improved by maintaining a flat geometry. This was accomplished by using a smooth flat block to flatten the bond area while it's in the capture tube. Although these catheters were better then the previous elliptical units they were not as good as the coaxial and could use some improvements. The guidewire movement was better than before but again not as good as the coaxial. The catheters did not track as well and seem to prolapse in the Aorta when the guide was backed out and force was applied to the catheter.

**Recommendation:** It was recommended that we evaluate different materials transitions and dimensions to reduce the prolapsing. Refine the inner member junction to improve wire movement. Another heart model was tentatively scheduled. (see heart model evaluation notes)

W. Chow 6/24/94

En Ullh 6/24/94